In the United States Court of Federal Claims

No. 20-499C

(Filed under seal: January 18, 2024)
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GILEAD SCIENCES, INC.,	)
Plaintiff,	)
v.	)
UNITED STATES,	)
Defendant.	)

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OPINION AND ORDER[1]

LETTOW, Senior Judge.

Pending before this court is the issue of the government's liability for breaching Clinical Trial Agreements ("CTAs") it had entered with plaintiff, Gilead Sciences, Inc. ("Gilead"). The issue of CTA liability has been fully briefed and is ready for disposition. *See* Pl. Gilead Scis.,

[1] Because of the protective order entered in this case, this opinion was initially filed under seal. The parties were requested to review the decision and provide proposed redactions of any confidential or proprietary information. No redactions were requested.

Inc.'s Suppl. Post-Trial Br. About the Gov't's Breach of the Clinical Trial Agreements ("Pl.'s Br."), ECF No. 171; Def.'s Opp'n to Pl.'s Suppl. Post-Trial Br. ("Def.'s Opp'n"), ECF No. 172; Pl. Gilead Scis., Inc.'s Reply in Supp. of its Suppl. Post-Trial Br. ("Pl.'s Reply"), ECF No. 176.

BACKGROUND

A. Procedural History

The case has been bifurcated into a liability phase and a separate damages phase. Hr'g Tr. 26:2-5 (Apr. 6, 2021), ECF No. 28. It is closely tied to a patent infringement case pending in the United States District Court for the District of Delaware. *United States v. Gilead Scis., Inc.*, No. 1:19-2103 (D. Del., filed Nov. 6, 2019). After holding a trial in June of 2022, this court issued an opinion regarding the liability phase of this case. *See Gilead Scis., Inc. v. United States*, 163 Fed. Cl. 104 (2022). The court held that the government breached three Material Transfer Agreements ("MTAs") between the government and Gilead, but "reserve[d] [its] decision on whether the government breached the CTAs," reasoning that "unresolved matters [related to CTA liability] presumably w[ould] be put before the [Delaware] district court in the patent trial, and that court then would have a better record for determination of the pertinent facts." *Id*. at 126, 128. The district court held its trial from May 2, 2023, to May 9, 2023. The jury in Delaware returned a verdict for Gilead on all issues put before it and entered judgment for Gilead on May 15, 2023. *See* J. following Jury Verdict, *United States v. Gilead Scis., Inc.*, No. 1:19-2103 (D. Del. May 15, 2023), ECF No. 471. The district court did not reach Gilead's equitable defenses,[2] although a complete record was made. *See* Bench Trial Tr. 386:22-24, 387:8-14, *United States v. Gilead Scis., Inc.*, No. 1:19-2103 (D. Del. May 9, 2023), ECF No. 485.

Gilead proposed a supplemental post-trial briefing schedule to resolve the CTA liability issue, acknowledging that the government "disputes whether any evidence introduced during the [Delaware] district court trial is relevant to the government's [alleged] breach of the CTAs, whether the [c]ourt may consider such evidence, and what effect it has on the CTA issues." Pl.'s Proposal for Resolving Liability and Commencing Damages Phase of Trial at 3, ECF No. 166. Gilead averred that its proposed schedule would enable the court to consider each party's written

[2] It is for this reason that any claim of collateral estoppel, as the government seeks to anticipate in its briefing, would fail. *See* Def.'s Opp'n at 23-24; *infra* at [7] n.6. Moreover, Gilead represents that "[t]here are no issues or challenges by the [g]overnment [in the Delaware case] that could affect a determination of this [c]ourt for the CTA liability." Hr'g Tr. 10:7-9 (Oct. 23, 2023), ECF No. 178. Nonetheless, this court recognizes that the government's post-trial motions for judgment as a matter of law, or alternatively for a new trial, in the Delaware case could implicate issues before this court. *See* Pl.'s Renewed Mot. for J. as a Matter of Law on Issues of Infringement, Anticipation, Obviousness and Enablement, or in the Alternative, Mot. for a New Trial, *United States v. Gilead Scis., Inc.*, No. 1:19-2103 (D. Del. June 20, 2023), ECF No. 488. In the Delaware case, should the government's motion for a new trial be successful and the outcome of that new trial be contrary to the current verdict, Gilead's equitable defenses would almost certainly be reached. Although this outcome is a possibility, it is not one that precludes this court from considering the issue of CTA liability at this time.

position on these issues in the context of the issues at hand, i.e., the admissibility and weight of the evidence relating to the government's liability under the CTAs. *Id.* at 3-4. Gilead also suggested that the parties file a joint status report on the damages phase of the case and participate in a damages scheduling conference after the court issues its opinion on CTA liability. *Id.* at 4-6.

The government has suggested that the court first open fact discovery for the damages phase of the case, and proposed a two-step briefing process with respect to CTA liability. First, Gilead would identify "every fact from the Delaware trial it intends to supplement the record with and any supporting legal basis" and the government would respond. Def.'s Proposed Reopening Schedule at 2, ECF No. 167. The parties would then file briefs "addressing how any identified facts affect the issue of CTA liability." *Id.* After the court issued an order deciding CTA liability, the government proposed that the court hold a status conference "to discuss remaining time necessary for fact discovery and to set [a] schedule for expert discovery and dispositive motions briefing." *Id.*

Ultimately, this court adopted Gilead's proposed schedule, as it represents a "streamlined yet comprehensive approach." Scheduling Order of Aug. 3, 2023 at 2, ECF No. 170. Following the conclusion of the parties' post-trial briefing, the court held a hearing on the issue of CTA liability on October 23, 2023.

B. The Clinical Trial Agreements

In 2004, Gilead and the government entered two CTAs governing the results of two clinical trials, known as the Extended Safety Study and the Botswana Study. The first trial was titled "Phase II Extended Safety of Tenofovir Disoproxil Fumarate (TDF) among HIV-1 Negative Men who have Sex with Men" ("Extended Safety Study"). *See* JX1 at 2.[3] The parties stipulated that this study was meant to discern the "clinical and behavioral safety and tolerability of administering once-daily oral tablet of 300 mg TDF in healthy men." *See* Am. Joint Stipulation ¶¶ 80-81. The second trial was titled "Study of Safety and Efficacy of Daily Tenofovir Disoproxil Fumarate ('TDF') for the Prevention of HIV Infection in Heterosexually-Active Young adults in Botswana" ("Botswana Study"). *See* JX2 at 2.[4] This trial first studied only TDF, but it was subsequently amended to study a combination of TDF and FTC (marketed as "Truvada®" and referred to as "TVD"). *See* JX8 at 1. The Botswana Study was amended two further times when Gilead agreed to provide additional study drugs. JX9, JX10.

The parties entered two separate CTAs, one governing each of the two studies at issue. Both CTAs contained the same Intellectual Property clause, the provision at issue here.

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[3] Citations to joint exhibits are shown as "JX"; defendant's exhibits as "DX." Citations to the transcript of the June 2022 liability trial are cited as "Tr. (Witness)."

[4] The Botswana Study is also referred to as the "TDF2" study or "TDF-2 trial." *See, e.g.*, Pl.'s Br. Ex. C, at 95, 156.

Following negotiations, the parties agreed that both Intellectual Property clauses would read as follows:

> Ownership of inventions from the Trial shall be determined in accordance with inventorship under U.S. patent law. The Study Drug and any related confidential information disclosed to [the Centers for Disease Control and Prevention ("CDC")] by Gilead will remain Gilead's property. *CDC agrees to put the results of the Trial, patentable or otherwise, in the public domain* for all to use without obligation or compensation to CDC. For clarity, *CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial*.

JX1 at 3; JX2 at 3 (emphasis added). The court addressed the obligations set forth by the cited language when it issued its Liability Opinion in November 2022. Specifically, this court concluded:

> The CTAs contain two separate but related obligations for the government. The first obligation is a requirement to put the results [of the Extended Safety and Botswana Studies] in the public domain. The second obligation is a prohibition on seeking patent protection on inventions derived from using TDF in the Extended Safety Study or TDF and FTC (Truvada) in the Botswana study. The second obligation clarifies, or builds upon, the first, and therefore the CTAs contain two separate obligations. The first requirement covers both patentable and unpatentable results, while the second prohibition covers only patentable inventions, since it puts any such inventions in the public domain and prohibits the government from seeking patent protection.

163 Fed. Cl. at 125-26. Put simply, the government was bound, first, to place the study "results" into the public domain and, second, not to seek patent protection for any inventions "derived from" the use of the study drugs in the studies. *Id.* [5]

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[5] The Liability Opinion defined both the terms "results" and "derived from." The Liability Opinion concluded the Extended Safety Study "results" "[are] that a daily TDF-based PrEP regimen was well tolerated, with reasonable adherence and [n]o significant renal concerns were identified in men who have sex with men." 163 Fed. Cl. at 124 (internal citations and quotation marks omitted). The Liability Opinion concluded the Botswana Study "results" "[are] that daily Truvada® [TDF and FTC] prophylaxis prevented HIV infection in sexually active heterosexual adults." *Id.* (internal citations and quotation marks omitted). The Liability Opinion adopted the parties' interpretation of the term "derived from" as possessing its "plain meaning." *See id.* at 125.

The government contends that Gilead is "asking the [c]ourt to reconsider the interpretation of the CTAs" at this stage, and correctly contends that such a reconsideration would be "[i]mproper[]." Def.'s Opp'n at 14-17. Nonetheless, the court does not understand Gilead as asking for a reconsideration of the prior decision regarding what the CTA obligations required, nor does the court make such reconsideration now. *See*, Pl.'s Reply at 1 ("Gilead is not

The Liability Opinion, however, reserved judgment on whether the government breached either or both of these two obligations in the CTAs, pending the outcome of the Delaware patent infringement trial. 163 Fed. Cl. at 126, 128. Specifically, the court determined that "there [was] insufficient evidence to determine if the government complied with the two obligations in the CTAs, to 'put the results in the public domain' for anyone to use without compensating CDC and 'not to seek patent protection in connection with any inventions that derive from use of the study drug in this trial.'" 163 Fed. Cl. at 126 (citing JX1 at 3; JX2 at 3).

Regarding the first obligation, this court found that "[a]lthough the results of the two trials relate to the content of the patented invention, the record [was] incomplete regarding whether the patent examiner took them into consideration and patented them when issuing the patent in 2015." 163 Fed. Cl. at 126. Regarding the second obligation, this court found that "there [was] insufficient evidence to determine" whether the patents were "'derived from' use of TDF in the Extended Safety Study or TDF and FTC in the Botswana study." *Id.* The court also noted with respect to the second obligation that "[w]hether the patent examiner was aware of the [Food and Drug Administration's ("FDA")] findings" regarding Truvada® "remains to be determined." *Id.* at n.28. In reserving judgment on these two issues, this court explained that "[t]hese unresolved matters presumably will be put before the [Delaware] district court in the patent trial, and that court then would have a better record for determination of the pertinent facts." *Id.* at 126. Ultimately, this court specified that the then-upcoming patent trial in the Delaware court could provide insight into these two key issues. Now that the Delaware court's patent trial has concluded, this court returns to the reserved issue of CTA liability.

C. The Delaware Trial

On May 3, 2023, the Honorable Maryellen Noreika of the Delaware District Court held a trial to determine whether Gilead had infringed on the government's patents "through the sale of Truvada® and Descovy®." *See* Compl. ¶ 9, *United States v. Gilead Scis., Inc.*, 1:19-cv-2103 (D. Del. Nov. 6, 2019), ECF No. 1. Following a multi-day trial, the district court found Gilead not liable for patent infringement. *See* Pl.'s Br. Ex. A, ECF No. 171-1. Because the district court returned a finding of no liability, it concluded there was no need to reach Gilead's equitable defenses, although they were presented and thus a record was created as to these arguments. *See* Pl.'s Br. Ex. B, at 387:4-14, ECF No. 171-2. In rendering its decision on the patent infringement claim, the district court considered various pieces of evidence, discussed below, some of which shed light on the two related issues of CTA liability.

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seeking reconsideration of anything. The evidence shows that the government breached ***both*** of its obligations for both CTAs under constructions of the CTAs that the [c]ourt has already adopted."). Nor is this court reconsidering the prior "freedom to operate" argument that the government contested in the past, and this court does not perceive Gilead as requesting it to do so. *See* Pl.'s Reply at 6 ("the government contends that Gilead is overreading the 'public domain' provision by equating it with 'freedom to operate,' but that too misunderstands Gilead's position. . . . The [c]ourt has already interpreted the CTAs to require the government 'to put the results in the public domain' [and] [t]hat is the only interpretation that Gilead advances.") (internal citations omitted) (first quoting Def.'s Opp'n at 14; then quoting 163 Fed. Cl. at 125).

STANDARDS FOR DECISION

A. Supplemental Briefing and Admissibility of Evidence

Under the Rules of the Court of Federal Claims ("RCFC"), this court has discretion to modify a post-trial briefing schedule to permit supplemental briefing. *See* RCFC 83(b) ("A judge may regulate practice in any manner consistent with federal law or rules adopted under 28 U.S.C. § 2072 or 2503(b)."); RCFC Appendix A, Case Management Procedure ¶ 19 ("The judge may order the filing of post-trial briefs . . . ."). Under Federal Rule of Evidence 201(b) the court may take judicial notice of a fact outside the record if it is either "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot be reasonably questioned." *See also St. Bernard Par. Gov't v. United States*, 121 Fed. Cl. 747, 769 (2015) (taking judicial notice of transcripts and exhibits from prior district court action); *Phonometrics, Inc. v. Hosp. Int'l, Inc.*, 120 F. App'x 341, 344-45 (Fed. Cir. 2005) (holding that the district court did not err in taking judicial notice of transcripts of prior court proceedings as sources "whose accuracy cannot reasonably be questioned").

B. Breach of Contract

To establish a claim for breach of contract, the plaintiff must prove four elements: "(1) a valid contract between the parties, (2) an obligation or duty arising out of the contract, (3) a breach of that duty, and (4) damages caused by the breach." *San Carlos Irrigation & Drainage Dist. v. United States*, 877 F.2d 957, 959 (Fed. Cir. 1989). As the plaintiff, Gilead bears the burden of proving each element. *See Beard v. United States*, 125 Fed. Cl. 148, 157 (2016). With respect to the first element, the government has stipulated that there were five valid agreements. Am. Joint Stipulation ¶¶ 23-109. As to the second element, this court has identified two distinct obligations arising out of the contract at issue. *See* 163 Fed. Cl. at 125. As to the fourth element, which will be separately assessed in the damages phase of these proceedings, Gilead must show that "(1) the damages were reasonably foreseeable by the breaching party at the time of contracting; (2) the breach [was] a substantial causal factor in the damages; and (3) the damages are shown with reasonable certainty." *Ind. Mich. Power Co. v. United States*, 422 F.3d 1369, 1373 (Fed. Cir. 2005). At this time, only the third element—whether the government breached its contractual duties—is at issue.

ANALYSIS

A. Admissibility of the Delaware Record

As the court has done in past cases, it may admit and consider evidence from a separate related trial. The Delaware trial record—including the trial transcripts and exhibits—is admissible, and the court may take judicial notice of it in deciding the issue of whether the government breached its CTA obligations.

Over the course of this litigation, the government has repeatedly suggested that this court should not consider the record created in the Delaware trial. *See, e.g.*, Def.'s Opp'n at 24-28; Hr'g Tr. 16:3 to 16:9 (July 25, 2023), ECF No. 169 (contesting "the basis for bringing in new evidence, particularly of witness testimony, which typically is not subject to judicial notice"). Specifically, the government objects to what it characterizes as a "blanket assertion" that this

court can and should take judicial notice of the Delaware trial record. Def.'s Opp'n at 24. The government opposes judicial notice on the basis that Gilead's "conclusory allegation" that the Delaware record's "'accuracy cannot reasonably be questioned' . . . fails to acknowledge that Gilead . . . is asking for this [c]ourt to take notice of underlying facts that Gilead alleges support its contentions that the CTAs were breached." *Id.* at 25 (quoting Pl.'s Br. at 27).[6] Gilead, however, contends the government's argument against judicial notice "is simply mistaken," noting that "[t]his [c]ourt may and should take judicial notice of the transcripts and exhibits from the Delaware trial," Pl.'s Br. at 27, and indeed that "courts routinely take notice of such documents." Pl.'s Reply at 14.

This court agrees with Gilead's assessment. Judicial notice of an underlying record cited over the course of post-trial briefing is permitted by the federal rules. As a threshold issue, the RCFC permits this court to order and consider post-trial briefing. *See* RCFC 83(b); RCFC Appendix A, Case Management Procedure ¶ 19. Moreover, Federal Rule of Evidence 201(b) permits the court to "judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Although "[m]atters of record in other courts are usually denied notice," *St. Bernard Par. Gov't*, 121 Fed. Cl. at 769 (quoting 2 McCormick on Evidence § 330 (7th ed. 2013)),[7] "the United States Court of Appeals for the Federal Circuit has taken judicial notice of proceedings before other courts and tribunals" in past cases. *See id*; *see also* Pl.'s Reply at 14-15 n.8.

Indeed, as Gilead has identified, the Court of Federal Claims and the Federal Circuit have previously deemed it proper to take judicial notice of facts set out in the record of another proceeding before a court or tribunal. For instance, in *St. Bernard Parish Government v. United States*, the Court of Federal Claims took judicial notice of the record of another case within the Eastern District of Louisiana, *Robinson v. United States*, noting that "[t]he [g]overnment has not

[6] The government also anticipates a collateral estoppel argument, contending that "[a]s there were no rulings on the merits of Gilead's CTA claims in Delaware, the doctrine of collateral estoppel cannot apply in this [c]ourt." Def.'s Opp'n at 24. Certainly, plaintiff has not raised, nor is this court considering, such an argument. *See generally*, Pl.'s Br; *see also* Pl.'s Reply at 2 ("The government asserts that collateral estoppel does not apply even though Gilead is not asserting it.") (internal citation omitted). Indeed, there has been no suggestion or indication that the issue of CTA liability has been conclusively resolved in a final judgment on the merits, such that the doctrine of collateral estoppel would be applicable. On the contrary, the issue of CTA liability has been left open both by the Delaware court and by this court. *See* Bench Trial Tr. 386:22-24, 387:8-14, *United States v. Gilead Scis., Inc.*, 1:19-2103 (May 9, 2023); *see also* 163 Fed. Cl. at 128.

[7] In relevant part, the McCormick treatise explains that "the claims made by the parties in the other case and action taken by the court in the other proceeding may be noticed," and that "[m]atters of record in other courts are usually denied notice even though it would appear manifest that these public documents are logically subject to judicial notice as to the indisputable information in them." 2 McCormick on Evidence § 330 (8th ed. 2022); *see also* Pl.'s Reply at 14-15 n.8.

argued that the *Robinson* evidence's accuracy can reasonably be questioned" and ruling that "[a]s such, . . . the proffered evidence from *Robinson* is 'not subject to reasonable dispute' and is subject to judicial notice." *St. Bernard Par. Gov't*, 121 Fed. Cl. at 769 (quoting Fed. R. Evid. 201(b)).[8]

In *Phonometrics, Inc. v. Hospitality Int'l, Inc.*, the Federal Circuit concluded that the district court had not erred "in taking judicial notice of facts in another case" when considering those facts in the process of rendering its own decision. *See* 120 F. App'x at 344-45 (Fed. Cir. 2005).[9] Specifically, the Federal Circuit explained that judicial notice was proper because, in taking such notice, "the district court merely recognized that the transcripts of prior court proceedings were sources 'whose accuracy cannot reasonably be questioned,'" rather than using the record to conclude that the finding of no liability "was indisputable from the statements" contained therein. *Id.* at 345 (quoting Fed. R. Evid. 201(b)).

Similarly, here, this court may take judicial notice of the record created in the Delaware trial not as dispositive on an issue of liability, but as a source "whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Indeed, as plaintiff itself concedes in its reply, "Gilead does not ask the [c]ourt to conclude that ***breach*** was indisputable from the Delaware transcript statements. Gilead simply asks the [c]ourt to recognize the transcripts as records of what the witnesses said, take notice of the testimony, and weigh that factual evidence as the [c]ourt always does when determining liability." Pl.'s Reply at 15. Gilead concedes that the underlying trial record would not be noticed for the underlying truth of the matter asserted, but rather as instructive to this court in making its own independent determination as to the ultimate issue of CTA liability. Indeed, this is precisely what this court can and will do.[10]

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[8] Here, the government likewise does not question the accuracy of the trial record itself in its briefs, so judicial notice should not be prevented on this basis. Indeed, as Gilead highlights, "[t]he government does not dispute the accuracy of the Delaware transcripts, and its cited cases agree that courts may 'take judicial notice of the indisputable fact that . . . testimony was given and says what it says.' That is what Gilead requests here." Pl.'s Reply at 15 (internal citation omitted) (quoting *Fed. Deposit Ins., Corp. v. FBOP Corp.*, 252 F. Supp. 3d 664, 706 (N.D. Ill. 2017)).

[9] While *Phonometrics* is a "nonprecedential decision," Def.'s Opp'n at 27 n.23, it is nevertheless still highly persuasive circuit authority that addresses analogous facts.

[10] The government also contends that Gilead's request for this court to judicially notice the Delaware trial record is "fundamentally flawed in that it fails to specify what precise facts this [c]ourt should judicially notice." Def.'s Opp'n at 27. The government bases its objection on the grounds that Gilead's apparently "vague[]" request "cuts against the tradition of caution underlying Rule 201(b)" and "is also disfavored because noticing records 'in their entirety' may 'yield unforeseen repercussions later in the litigation.'" *Id.* (quoting *Barnett v. United States*, 650 F. Supp. 3d 412, 440 (D.S.C. 2023)). This court, however, disagrees that it "can reject all of Gilead's requests for judicial notice on this basis alone." *Id.* at 28. This court is not taking notice of the entire record generated in the Delaware trial, but rather the specific portions thereof

The fact that the government disagrees with the underlying evidence presented in the Delaware trial, or Gilead's characterization thereof, however, is not in itself a basis to bar this court from taking notice of the record. While the government may indeed be correct that the underlying facts presented in the Delaware trial "cannot be noticed for the truth of the matter asserted," Def's Opp'n at 26, this simply misunderstands the basis for this court taking judicial notice of the Delaware record. This court takes notice of the Delaware record not for the truth of matters asserted, but rather to independently determine the credibility and weight of such evidence. As is evident from precedents that the government itself cites, taking notice of the "existence" of documents submitted in an outside proceeding is permissible. *See Consumers Energy Co. v. United States*, 65 Fed. Cl. 364, 369 n.7 (2005) (cited in Def.'s Opp'n at 26).

Moreover, the government's argument opposing judicial notice fails as a practical matter. As both parties have recognized, this court specifically reserved judgment on the issue of CTA liability pending the resolution of the Delaware trial. 163 Fed. Cl. at 126. As such, this court can and will take judicial notice of the Delaware trial record, together with the record before this court, to assess the government's CTA liability.

B. Whether the Government Breached the CTAs

The court assesses whether the government breached its two CTA obligations considering the factual record, as completed by evidence from the Delaware trial. Ultimately, this court concludes, based on the evidence presented, that the government breached both of its CTA obligations.

The government's first CTA obligation is "to put the results of the Trial[s], patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC." JX1 at 3; JX2 at 3.[11] As this court determined, this means the government must put the results of the Extended Safety and Botswana Studies in the public domain, rather than seeking patent protection for them. *See* 163 Fed. Cl. at 125. Under its second obligation, the government "agree[d] not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." JX1 at 3; JX2 at 3. This court determined that this obligation—understood by reference to the plain meaning of "derived from"—"is a prohibition on seeking patent protection on inventions derived from using TDF in the Extended Safety Study or TDF and FTC (Truvada) in the Botswana study." 163 Fed. Cl. at 125.

In determining whether the government breached its first obligation, the court considers whether the evidence supports a finding that the patent examiner considered the trial results in his assessment, such that the results were removed from the public domain when the patents

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that Gilead cited in its briefing. *See generally* Pl.'s Br.; *see also* Hr'g Tr. 46:11-12 (Oct. 23, 2023).

[11] As Gilead notes in its reply, the government's contention that it satisfied its first CTA obligation because it "published" the study results is unavailing. Pl.'s Reply at 3 (quoting Def.'s Opp'n at 6). Indeed, publication does not fulfill the government's first obligation if those published results cannot be freely used by the public.

issued. In determining if the government breached its second obligation, the court considers whether the evidence supports a finding that the government sought to patent inventions that derived from the results of either or both the Botswana and Extended Safety Studies. The court concludes that, taken as a whole, the evidence does support such findings.[12]

In its supplemental briefing, plaintiff argues two main categories of evidence support the showing that the government breached the CTAs: (1) Delaware trial testimony from lead inventor Dr. Walid Heneine and others regarding the nature of the clinical trials; and (2) the patents' file histories, suggesting the patent examiner considered articles citing the clinical trials as well as the FDA's approval of Truvada® for PrEP in assessing four CDC patent applications. *See* Pl.'s Br. at 15-23.

In its Liability Opinion, this court concluded that, at the time, there was insufficient evidence to determine whether either or both of the government's CTA obligations had been breached. *See* 163 Fed. Cl. at 126. Accordingly, this court reserved judgment to allow the record to be more fully developed following the Delaware trial. *Id.* This court left open the type of evidence that might bear on whether the government breached the CTAs. As such, the government's argument, that evidence from the Delaware trial is not "materially new" is unavailing. As discussed further, while some of the new evidence that plaintiff identifies is similar to that which this court has previously considered, the addition of this evidence renders the evidentiary record sufficiently well-developed for the court to determine whether the government breached one or both of its obligations under the CTAs.

1. *Delaware trial testimony regarding the relationship between the clinical studies and the patented invention*

The first body of evidence Gilead addresses from the Delaware trial concerns the nature of the Botswana and Extended Safety Studies and their role in advancing the research that resulted in the drug combination the government ultimately claimed in its patent. As Gilead characterizes it, the Botswana Study "investigated and proved" the efficacy of the combination of TDF and FTC for PrEP, and the Extended Safety Study "proved the safety of TDF for PrEP." Pl.'s Br. at 16. Gilead contends the testimonial evidence it identifies shows the patent-at-issue derived from the findings resulting from both the Extended Safety and Botswana Studies. *See id.* at 17-19. Specifically, Gilead contends that the Extended Safety Study results, "which proved that uninfected men could safely use TDF long-term," were "foundational to establishing the viability of a TDF-based PrEP regimen," *id.* at 17, and that "[t]he Botswana results supported CDC's patent claim for methods for PrEP in all people, including heterosexual men and women." *Id.* at 18. Gilead relies on testimony from Drs. Folks and Heneine confirming that "subsequent clinical trials in humans . . . were needed to determine the efficacy of the

[12] Notably, the government contends it did not breach the CTAs by filing the provisional and non-provisional applications in 2006 and 2007, respectively, because the results of the Botswana and Extended Safety Studies were not then finalized and "the July 2014 amendments," filed once the results were finalized, "did not alter the scope of the claimed invention." *See* Def.'s Opp'n at 15-16. But this court has already rejected this argument because "[t]he 2014 patent application, which completely amended the applications, was filed after the final data in the two CTA trials had been collected and results had been published." 163 Fed. Cl. at 126.

combination [of TDF plus FTC] in humans," Pl.'s Br. Ex. D, at 213:1-10 (Folks), and in fact that "it was 'only with human clinical trials that you could ultimately determine the efficacy of TDF and FTC for PrEP.'" *See* Pl.'s Br. at 16 (quoting Pl.'s Br. Ex. D, at 331:15-22 (Heneine)). Gilead contends this testimony demonstrates that clinical studies were necessary for patents claiming those specific results to issue and that, when those patents ultimately did issue, they "remove[d] the Botswana and Extended Safety Study results from the public domain." *Id.*; *see also id.* at 18-19 ("[T]he [patent] ***claims*** cover use in all genders, and . . . all the clinical trials must be read together to prove efficacy in all populations. Accordingly, the Patents-at-Issue derive from the results of the Botswana Study."). According to Gilead, CDC breached the CTAs simply by patenting the results of the clinical trials "regardless of what information CDC submitted to the Patent Office." *Id.* at 16.

The government argues that the testimony that human clinical trials were needed to determine the efficacy of the TDF and FTC combination "is not materially new evidence," as this court's trial transcript "already contains testimony from Dr. Heneine on this same issue as well as testimony from Gilead's own witness." Def.'s Opp'n at 19 (internal citations omitted). The government also highlights its direct reliance on other studies cited in its patent applications, namely the subsequent Partners PrEP and iPrEx studies, to suggest that these studies, rather than either the Botswana or Extended Safety Studies, formed the basis of the patent applications. *See id.* at 19 ("Dr. Heneine explained that the iPrEx clinical trial was appropriately cited because it was the most comparable clinical trial" and, "in contrast to iPrEx and Partners PrEP (the two principal clinical trials relied on by FDA for efficacy), the agency reviewed the Extended Safety Study for safety of TDF alone, not efficacy") (internal citations omitted).

The relationship among study results, however, cannot be compartmentalized so discretely.[13] Rather, the reality is necessarily more organic: had the prior Botswana and Extended Safety Studies shown that the study drugs were ineffective or unsafe, the latter Partners PrEP and iPrEx studies would have been foreclosed. *See, e.g.*, Tr. 871:13-24, 884:1-6, 889:4-12, 891:1-22 (Celum); Tr. 1561:19-20 (Grant); *see also* Pl.'s Reply at 8 ("[T]he iPrEx results would not have been possible without the Extended Safety Study. . . without which the other studies could not have been completed or patents issued"). Ultimately, this court accepts Gilead's claim that "if TDF was shown not to be safe then it would affect 'other ongoing PrEP studies evaluating the efficacy of TDF-based PrEP regimes,' as well as the use of TDF and FTC in the Botswana study, because that study included women and the patent covered all people." 163 Fed. Cl. at 125 (citing Pl.'s Post-Trial Br. at 53-54, ECF No. 136); *see also* Hr'g Tr. 37:3-24

[13] Gilead also addresses this court's past observation that the government's lack of direct citation to the two studies at issue may have been a "matter of avoidance." Pl.'s Br. at 23 (quoting 163 Fed. Cl. at 125); *see also* Pl.'s Br. at 9-10. Whether the government deliberately failed to disclose these sources in patent applications is not the central issue of this opinion, and the court agrees that such a conclusion would require "an inferential leap." Def.'s Opp'n at 18. Nor does this court need to conclude as much to find CTA liability, as Gilead itself concedes. Pl.'s Reply at 10. This possibility, however, does undermine the government's argument relying on the lack of a direct citation to the studies. Indeed, the lack of direct citation is not necessarily in itself a basis to conclude that the studies were not relied upon in light of the evidentiary context as a whole.

(Oct. 23, 2023). That is, because the studies demonstrated that TDF and the TDF and FTC combination are safe, they are an important and necessary step in reaching the claimed invention.

Further, the narrowed claims submitted to the Patent Office for consideration in July 2014—"years after the conclusion of the Botswana and Extended Safety Studies," Pl.'s Br. at 12—necessarily relied upon the results of the two studies. Specifically, the two studies, taken together, showed "that oral TDF was safe for long-term use in uninfected men," and "that '[d]aily [oral] TDF-FTC prophylaxis prevented HIV infection in sexually active heterosexual adults." 163 Fed. Cl. at 126 (quoting DX1090 at 14). As Gilead argues, the Botswana Study's finding "that oral TDF and FTC could be effectively used for PrEP" was "essential to 'ultimately determine the efficacy of TDF and FTC for PrEP' in humans, as claimed in the government's patents." *See* Pl.'s Br. at 7 (quoting Pl.'s Br. Ex. D, at 331:19-22 (Heneine)) (citing Pl.'s Br. Ex. D, at 356:8-357:1 (Heneine), 213:1-13 (Folks)). Put simply, without the results of the Botswana and Extended Safety Studies, the claim placed before the patent examiner for consideration would not have been possible. Indeed, as Dr. Heneine testified, only a human-based study such as the Botswana Study, could have produced such conclusions. *See* Pl.'s Br. at 16 (quoting Pl.'s Br. Ex. D, at 331:15-22 (Heneine)).[14] Additionally, the Notice of Allowance issued in January of 2015[15] was based only on the "entirely new," narrower, claims submitted after the Botswana and Extended Safety Studies had concluded. *See* 163 Fed. Cl. at 118.[16] This suggests that the patent examiner, in issuing the 2015 patent, had narrowed his focus to specifically consider the conclusions supported by the two studies. Thus, the Botswana Study, which assessed the combination of TDF and FTC, necessarily built upon the Extended Safety Study, which assessed the safety of TDF alone, and the conclusions of both studies with respect to humans were needed for the patented claim.

As is permissible under the evidentiary rules, this court is independently assessing the credibility of witness testimony in the Delaware trial. The crediblity of this testimony is enhanced by the fact that the witnesses offered consistent characterizations of the Botswana Study's role in developing the patented drugs over time and across the two trials. The consistency of the testimony regarding the clinical studies' significance is more compelling because the the two trials involved distinct claims and issues—one concerned breach of contract, the other patent infringement. Ultimately, the consistent testimony regarding the relationship

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[14] As Gilead further articulates in its reply, "the Botswana Study was necessary support for the government's new claims, irrespective of whether it was cited during prosecution." Pl.'s Reply at 12.

[15] A Notice of Allowance indicates that an underlying patent application "has been examined and is allowed for issuance as a patent," and that "prosecution on the merits is closed," but "is not a grant of patent rights." JX23 at 779.

[16] As Gilead identifies in its reply, the government's amendments are also relevant to its second obligation to refrain from seeking patent protection for claims "derive[d] from" the trial results. Pl.'s Reply at 13. As such, it should be noted that the discussion of the amendments with respect to the government's first obligation is not mutually exclusive with the government's second obligation.

between the human clinical trials at issue and the patented invention indicates the government used the study results in a manner that breached its CTA obligations.

2. *Patent file history evidence regarding the patent examiner's awareness of and reliance on the results of the clinical trials*

Gilead next argues that the patent file histories show the patent examiner considered the results of the Botswana and Extended Safety Studies in issuing the patents. Gilead relies on evidence showing that the government submitted, and the patent examiner considered, numerous citations to the Botswana Study, as well as the FDA's approval of Truvada® for PrEP, in contravention of the government's obligations under the CTA agreements.

First, Gilead presents evidence from the Delaware trial indicating that the CDC submitted numerous articles citing the studies at issue in its patent applications. Gilead highlights the fact that a 2013 article by Ivana Massud (the "Massud article") was submitted with each of the CDC's patent applications, including its narrowed 2014 amendments. *See* Pl.'s Br. at 19.[17] This article "cited the Botswana Study to show that 'clinical trials with daily FTC/TDF among men who have sex with men and heterosexually active men and women have provided proof of concept that daily PrEP can prevent sexual HIV transmission.'" *Id.* (quoting JX23 at 670) (citing JX23 at 677). Gilead avers that the citations to the Massud article tend to show that "evidence of the Botswana Study was before the patent examiner at least by July 2014," thus "placing it (and its discussion of the Botswana Study) in front of the examiner on at least four occasions." *Id.* Including the Massud article, Gilead further claims that "the government submitted documents that cited the Botswana Study" to the patent examiner a total of "***thirteen*** times across the four Patents-at-Issue" in addition to prior submissions which "discussed the ***expected*** results of the Botswana and Extended Safety Studies." *Id.* at 20; *see also* Hr'g Tr. 20:18-25 (Oct. 23, 2023) ("These patent file histories demonstrate that the [g]overnment repeatedly submitted documents citing the Botswana study to the Patent and Trademark Office and that the patent examiner . . . actually considered" and "explicitly acknowledged considering those results . . ."). Accordingly, Gilead contends, the patents' file histories show "the patent examiner repeatedly 'considered the results' of the [Botswana Study] during prosecution of and in allowing the CDC patent applications." Pl.'s Br. at 21 (quoting 163 Fed. Cl. at 126). By supporting its application with sources citing the study results, the government removed those results from the public domain once the patents issued, and those seeking to use the drug combination could not do so without compensating the CDC. *Id*.

Second, Gilead highlights an exhibit presented at the Delaware trial indicating that "the patent examiner was not only aware of FDA's approval of Truvada® for PrEP, but also knew that FDA had considered the results of the Botswana and Extended Safety Studies when approving Truvada® for PrEP." Pl.'s Br. at 21-22; Pl.'s Br. Ex. C, at 404 ("FDA did not approve the combination of TDF and FTC for prevention until 2012; this approval was based on clinical

[17] While the fact that the Massud article was cited in the issued patent application was already known to and considered by this court prior to the Delaware trial, *see* 163 Fed. Cl. at 125 n.28, the court now considers this citation not in isolation but together with various other materials.

trials conducted due to the results presented in the present application."). Notably, Gilead contends that it was not until "[a]fter the government pointed the patent examiner to those clinical trials" that "the Patent Office issued the '333 Patent." *Id.* at 22 (citing Pl.'s Br. Ex. C, at 438-47). As such, Gilead argues "[t]his shows that the patent examiner 'had access to the FDA's findings and conclusions,' which were based on the Botswana and Extended Safety studies, and considered those findings in issuing the CDC patents," and consequently that "the patents derived from the Botswana and Extended Safety Study results, which FDA's approval memo prominently cited." *Id.* at 22-23 (quoting 163 Fed. Cl. at 125 n.28).

The government claims that its submission of articles citing to the Botswana Study thirteen times across the four Patents-at-Issue is "insignificant." Def.'s Opp'n at 20 n.17. Specifically, the government contends that these thirteen citations "merely contain[] cumulative material . . . because [they were] cited 'for a similar proposition'" as articles cited in past application materials. *Id.* at 20, 20 n.17; 163 Fed. Cl. at 126 n.29; *see also* Hr'g Tr. 62:1 to 62:17 (Oct. 23, 2023) (characterizing additional references as "duplicative"). Moreover, the government minimizes the significance of the citations to the Botswana Study within one citation—the 2014 article authored by Chastity Andrews—by noting that the article "principally addresses PrEP research regarding the use of an unrelated [drug]" and that "the Botswana Study is the fifth of five studies briefly mentioned." Def.'s Opp'n at 21.

In response to the evidence regarding FDA approval, the government avers that "Gilead's theory is not supported by the record and it greatly overstates the importance FDA placed on the Botswana and Extended Safety Studies in approving Truvada for PrEP." Def.'s Opp'n at 19. Moreover, the government claims that generic statements in the patent prosecution histories that the FDA's approval was based on clinical trials do not "prove[] that the [e]xaminer actually considered the Extended Safety Study or the Botswana Study when issuing the HHS Patents." *See id.* at 21; *see also* Pl.'s Br. Ex. C, at 404.

Collectively, the references to the Botswana and Extended Safety Studies in the patents' file histories that Gilead identifies suggest the government relied on the study results in subsequent patent submissions.[18] Overall, the key claims of the articles submitted as part of the

[18] Gilead also contends the Delaware trial showed that Dr. Heneine and other inventors were closely familiar with the results of the studies throughout the course of the patent process, suggesting that they were relied upon therein. *See* Pl.'s Br. at 24-25. Gilead posits that "the Delaware trial confirmed that Dr. Heneine was aware of the Botswana and Extended Safety Studies and their results by the mid-2000s—around the time of the provisional and non-provisional applications, and long before the filing of the amended application in 2014." *Id.* at 24. Specifically, Gilead cites testimony of Dr. Heneine in which he confirmed his knowledge that "CDC was conducting clinical trials regarding Truvada for PrEP in the mid to late 2000s," and "one of those clinical trials was the Botswana trial." Pl.'s Br. Ex. B, at 302:12-23 (Heneine), cited in Pl.'s Br. At 24. While the inventors may have been intimately familiar with the studies, and aware of their results over the course of the various patent applications, this evidence alone does not establish that the subsequent inventions "derived from" these results.

patent applications derived from the covered study results.[19] That "the government submitted documents that cited the Botswana Study ***thirteen*** times across the four Patents-at-Issue" makes it particularly likely that the patent examiner not only considered but relied upon the results of those studies in issuing the patent. Pl.'s Br. at 20-21. And indeed, the patent examiner himself confirmed that "all references [were] considered except where lined through," and the references citing the Botswana Study were not lined through. *See* Pl.'s Br. Ex. C, at 290-91; Hr'g Tr. 26:9-11 (Oct. 23, 2023).

The government's reliance on articles citing these studies' results over the course of multiple patent applications suggests the government itself viewed the studies as strong, pertinent evidence supporting its patent claims. Moreover, the government's submissions reveal a practice of building upon the actual and anticipated results of these studies in its patent application endeavors. *See* Pl.'s Br. at 20-21. This practice reflects the incremental nature of scientific progress and belies the government's arguments that the invention ultimately patented is too far removed from the study results to be considered "derived from" them under the CTAs.

Moreover, the multiple sources that specifically referenced the Botswana Study results collectively indicate the government's reliance on these results was not by happenstance—such as via a stray footnote in the Massud article—but rather by design. Put differently, these sources necessarily derived from the study results, and the government placed the results before the patent examiner for consideration by relying on articles which in turn discussed these results. Therefore, the patent examiner considered material which derived from the study results.

The government fails to rebut this strong showing. Specifically, that these citations "contain[] cumulative material" tending to show a "similar proposition" as past source citations, Def.'s Opp'n at 20, makes it more likely that the examiner actually considered these citations. As Gilead avers in its reply, "'cumulative' evidence matters here: [t]he [p]atent [e]xaminer might have missed ***one*** footnote citation, but when confronted with the Botswana results ***thirteen*** times, the [e]xaminer must have considered them in allowing the government's patents." Pl.'s Reply at 6. And as plaintiff argued in the CTA liability hearing, although the government "is trying to limit the importance of the Botswana study," the articles the government cited which reference that study "boil the Botswana study down to what it stands for, to . . . its most significant part," the summary of its results. *See* Hr'g Tr. 69:1-9 (Oct. 23, 2023). Moreover, the more frequently a study result is cited in a patent application, the more likely the applicant views those results as essential to their application, and the more likely the patent examiner actually considered the results in making his patent assessment.[20]

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[19] Indeed, as plaintiff explained during the CTA liability hearing, these references were "not . . . in the middle of a text or something. They're at the very beginning. They're in the very opening. So there's no doubt that what they're trying to show is critical. These results are critical to one of the main theses of these articles." Hr'g Tr. 29:10-16 (Oct. 23, 2023).

[20] This is especially the case when, as Gilead highlights, "[t]wo of the articles" cited before the patent examiner "even mention[ed] the [Botswana] study by name on their first page," thus making its citation even more prominent. Pl.'s Reply at 5 (citing Pl.'s Br. Ex. C, at 95, 156) (referencing the Botswana Study as the "TDF2 studies" or "TDF-2 trial").

Similarly, the government's argument that the Botswana Study citation is insignificant because it appears as one in a series of citations is unavailing. Def.'s Opp'n at 21. In fact, that multiple citations support a proposition does not necessarily weaken the justificatory strength of each individual citation. On the contrary, the court agrees with plaintiff's characterization that "[i]t's not cumulative when you say something over and over again in support of your theory." Hr'g Tr. 69:14-16 (Oct. 23, 2023). Concluding otherwise would be analogous to determining that a citation presented to a court in a string-cite format is in some sense less compelling than a singular citation standing on its own. Such a conclusion would be unreasonable and indeed incorrect. Similarly, here, what matters is simply that the Botswana Study was repeatedly cited in materials before the patent examiner, whether alone or in conjunction with other citations.

Next, the court finds that the patent examiner was aware of the FDA's findings. Evidence from the Delaware trial emphasized that the government pointed out the results of "clinical trials" which "included the Botswana and Extended Safety Studies, both of which FDA discussed in its approval memo." *See* Pl.'s Br. at 22. Specifically, the inventors noted in their written submission to the patent examiner that "FDA did not approve the combination of TDF and FTC for prevention until 2012; this approval was based on clinical trials conducted due to the results presented in the present application." Pl.'s Br. Ex. C, at 404. Notably, this remark would have focused the patent examiner's attention on the FDA's approval of the combination drug following the clinical trials. The FDA's approval resulted from the clinical trials, and information regarding its approval was certainly before the patent examiner. Indeed, as this court has previously recognized, the FDA approval memo is significant because it was issued following a request for "information about the results of the Extended Safety Study and the Botswana Study as they related to Truvada for PrEP." 163 Fed. Cl. at 115 (internal citations omitted). Importantly, the evidence shows the inventors drew particular attention to the FDA's approval, noting that "'[s]ubmitted herewith is the FDA news release of the approval of tenofovir disoproxil fumarate and emtricitabine . . . dated July 16, 2012.'" Pl.'s Br. at 22 (quoting Pl.'s Br. Ex. C, at 404). That the inventors explicitly directed the patent examiner's attention toward the news of the FDA's approval, which "depended on the study results," Pl.'s Reply at 11, indicates the inventors found this approval significant enough to highlight for the patent examiner. As such, the evidence shows that the patent examiner was indeed deliberately presented with, and thus aware of, the FDA's safety and efficacy findings which in turn stemmed from the Botswana and Extended Safety Studies. Therefore, the patent examiner considered material which directly derived from the two studies at issue, in contravention of the government's obligations under the CTAs.

The government's assertion that Gilead "greatly overstates the importance FDA placed on the Botswana and Extended Safety Studies in approving Truvada for PrEP" fails. Def.'s Opp'n at 19. In delaying its finding regarding "[w]hether the patent examiner was aware of the FDA's findings," 163 Fed. Cl. at 125 n.28, this court did not require a showing of any specific level of awareness or reliance on the covered study results. Rather, the court merely acknowledged that the Delaware trial could produce additional evidence indicating that the examiner was aware of these findings. The patent file histories show that the government specifically directed the patent examiner's attention to the study results in the subsequent prosecution of the '333 patent. *See* Pl.'s Br. Ex. C, at 404. This suggests that the government itself viewed these findings sufficiently important to emphasize in its application materials. Next, the government's argument that Gilead fails to cite specific evidence proving that the

patent examiner actually *considered* the FDA approval is similarly unconvincing. Def.'s Opp'n at 22.[21] Indeed, as Gilead highlights, the patent examiner indicated that the applicant's amendments and remarks—including those regarding FDA approval—had been "fully considered" and found persuasive. Pl.'s Br. Ex. C, at 438-48; Pl.'s Br. at 14; Pl.'s Reply at 5 n.3. Within this context, there is no reason to believe that, of all the material placed before the patent examiner, the FDA's approval would be the one piece of evidence that the examiner would not have considered. As such, this court concludes that the patent examiner considered the FDA approval which resulted from the clinical trials.

Taken together, Delaware trial testimony and patent file histories confirm that the Botswana and Extended Safety Study results were necessary, and indeed significant, steps in generating the "content of the patented invention" and that the patent examiner in fact considered the results of the studies in issuing the patents. 163 Fed. Cl. at 126. As such, by pursuing the at-issue patents, the government removed the results of the clinical studies from the public and sought patent protections for inventions derived from the clinical studies in violation of both its obligations under the CTAs.

CONCLUSION

For the reasons stated, the court finds that the record created in the Delaware trial can be considered in this court. The court also finds that considering this evidence, the government breached both of its obligations under the CTAs.

The parties are requested to submit a joint status report on the damages phase of the proceedings on or before February 1, 2024.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Senior Judge

[21] The government also, at various points, characterizes the court's reservation as to CTA liability as a directive that Gilead itself furnish specific additional evidence. *See, e.g.*, Def.'s Opp'n at 22 ("Gilead failed to provide testimony from any fact or expert witness on whether the prosecution histories of the '333, '191, or '423 patents have any bearing on the CTAs. This is a glaring omission in view of this [c]ourt's express charge to Gilead to obtain more evidence of '[w]hether the patent examiner was aware of the FDA's findings.'") (quoting 163 Fed. Cl. at 125 n.28); *id.* at 23 ("Gilead ignored this [c]ourt's admonition to develop 'a better record for determination of the pertinent facts.'") (quoting *id*. at 126). On the contrary, in reserving judgment as to the issue of CTA liability, this court was merely reserving its decision as to this aspect of the case until the Delaware trial had concluded, based on the possibility that evidence from that trial could provide additional evidence bearing on the issue in this case. *See id*.